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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,775	06/30/2003	John C. Hill	084.0004X1 (FLORA.1300)	1915
Ingrassia Fisher & Lorenz, P.C. (FLORATECH) 7010 East Cochise Road			EXAMINER	
			GHALI, ISIS A D	
Scottsdale, AZ 85253-1406			ART UNIT	PAPER NUMBER
			1611	
		NOTIFICATION DATE	DELIVERY MODE	
			01/24/2011	ELECTRONIC

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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		Application No.	Applicant(s)			
Office Action Summary		10/611,775	HILL ET AL.			
		Examiner	Art Unit			
		Isis A. Ghali	1611			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) 又	Responsive to communication(s) filed on <u>04 No</u>	ovember 2010.				
•		action is non-final.				
′ —	, <del>-</del>					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
4) 🛛	4)⊠ Claim(s) <u>35,36,38 and 39</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)	Claim(s) is/are allowed.					
6)🛛	Claim(s) 3,36,38 and 39 is/are rejected.					
· ·	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restriction and/or	election requirement.				
Applicati	on Papers					
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority ι	ınder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachmen	t(s)					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date						
	2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Notice of Draftsperson's Patent Drawing Review (PTO-948)  5) Notice of Informal Patent Application					
Paper No(s)/Mail Date <u>12/10/2010</u> . 6) Other:						

#### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment filed 11/04/2010, and IDS filed 12/10/2010.

Claims 35, 36, 38, and 39 are pending and included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 35, 36, 38 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 12/203,004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: composition comprising saponified jojoba oil fraction and non-saponified jojoba oil fraction. The present claims anticipate the copending claims.

Art Unit: 1611

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 35, 36, 38 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 12/080,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: composition comprising saponified jojoba oil fraction and non-saponified jojoba oil fraction. The present claims anticipate the copending claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The examiner acknowledged applicant's deferral the response to provisional obviousness double patenting rejection till indication of patentable subject matter in any of the applications. Therefore, the rejections are maintained.

## Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1611

6.

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to

comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. The amended claim 35 recites "saponifiable

that are produced as tandem reaction product....". Applicant refers to page 14, lines 6-

15 for support, however, no support found in page 14 or any where in the specification.

Page 14, lines 6-15 of the specification discloses:

"Jojoba oil may be examined as an example case. Refined jojoba oil contains various proportions of long chain diunsaturated esters. Hydrolysates of refined jojoba oil are nearly a 55:45 mixture of polar hydrophilic long chain salts (alkali salts) and relatively non-polar lipophilic materials (fatty alcohols). The lipophilic fraction is the unsaponifiable materials according to the definition used in this document. The carbon chain lengths of both of these jojoba Hydrolysates include and vary from  $C_{18}$  to  $C_{24}$  and have  $\omega$ -9 double bonds as part of each molecule. It has been found that the combination of saponifiable and unsaponifiable fractions of the Hydrolysates according to the present invention has properties that aid in the formulation of cosmetic, pharmaceutical, and other compositions."

Therefore, no disclosure of saponifiable that are produced as tandem reaction product....". If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

Art Unit: 1611

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 10. Claims 35, 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over FR 2471775 ('775) as evident by O'Connor et al. "Long-chain unsaturated alcohols

from jojoba oil by sodium reduction", currently provided, or as evident by Daugherty et al. "Industrial raw materials of plant origin", currently provided", and in view of US 6,280,746 ('746).

### **Applicant Claims**

Applicants' currently amended claims 35 is directed to a method for preparing a topical formulation, said method comprising the steps of: obtaining a composition comprising alkali salts of jojoba fatty acids and non-polar unsaponifiables that are produced as tandem reaction products from saponification of jojoba oil, the jojoba oil comprising at least 6 weight percent non-polar unsaponifiables prior to saponification; and neutralizing an acidic gelling agent in said topical formulation with an effective amount of said composition; wherein said topical formulation comprises the composition and the acidic gelling agent.

Currently amended claim 38 is directed to a method for preparing a topical formulation, said method comprising the steps of: obtaining a composition comprising a mixture of alkali salts of jojoba fatty acids present in an amount of about 55 percent by weight of the composition and long carbon chain unsaponifiable material present in an amount of about 45 percent by weight of the composition, wherein the long carbon chain unsaponifiable material is obtained from saponified jojoba oil, the saponified jojoba oil comprising at least 6 weight percent long carbon chain unsaponifiable material prior to saponification, said long carbon chain unsaponifiable material comprising at least 18 carbons in length; and neutralizing an acidic gelling agent in a topical

formulation with an effective amount of said composition, wherein the topical formulation comprises the composition and the acidic gelling agent.

# Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

FR '775 teaches cosmetic composition comprising mixture of jojoba oil and sunflower oil, and from 20-40% unsaponifiables oils fractions (page 4, 3<sup>rd</sup> paragraph). The unsaponifiable fraction includes residual part of saponifiable components and unsaponifiable fraction, with the **unsaponifiable** ingredients is **greater than 40**% (paragraph bridging pages 4 and 5). FR '775 teaches composition comprising saponifiable and unsaponifiables fractions obtained from vegetable oils and suggested jojoba oil. The cosmetic composition can be in the form of gel (last paragraph of page 5). Examples 3-5 and 7 showed composition comprising gelling agent Caropol 940, which is an acidic gelling agent. The reference teaches that unsaponifiables display interesting dermatological properties and used in cosmetics (page 3, 5<sup>th</sup> paragraph).

Jojoba oil taught by FR '775 contains non-saponifiable fraction of fatty alcohol having  $C_{20}$ - $C_{22}$  carbons as evident by O'Connor who teaches that hydrolysis of jojoba oil provides alcohol of high unsaponifiable value and low free fatty acids (see the entire document, especially page 381, left column). This fact is also evident by the teaching of Daugherty who teaches that jojoba oil (*Simmondsia chinensis*) contains fatty acids (saponifiable) having  $C_{16}$ - $C_{18}$  carbons and 37.62-48.3% fatty alcohols (non-saponifiable)

having C<sub>20</sub>-C<sub>22</sub> carbons (see table 1 at page 297 and 299, left column). The teaching of Daugherty implies that jojoba oil contains 62-38-51.7% saponifiable fatty acids.

# Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although FR '775 teaches composition comprising saponifiable and unsaponifiables fractions obtained from vegetable oils and suggested jojoba oil, however, the reference does not explicitly teach pretreatment, such as hydrolysis of the oil. Jojoba oil contains both saponifiable and non-saponifiable fractions as evident by the teachings of O'Connor and Daugherty,

US '746 teaches cosmetic composition comprising jojoba oil (abstract). When applied to the skin, the cosmetic composition comprising jojoba oil prevents and retains natural moisture level of the skin (col.8, lines 18-24). The composition comprising jojoba oil esters from the trade name Floraesters-15, 20, 30, 60 70 (col.8, lines 35-40). The reference disclosed that jojoba oil can be catalyzed, i.e. hydrolyzed, using alkali metal hydroxide, as applicants had done (col.3, lines 53-60). The reference disclosed gel comprising Carbopol (example 2). The Floraester disclosed by the reference are expected to have salt of saponifiable jojoba fatty acids and unsaponifiable fractions of jojoba oil, and expected to comprise at least 6% long chain carbon material prior to hydrolysis, since applicants exemplified and practiced their invention using such trade name product. Hydrolyzed jojoba esters are produced using potassium hydroxide, and

... .....

therefore they are alkaline and will display the property of neutralizing acidic gelling agent.

# Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gel cosmetic composition comprising saponifiable and unsaponifiable oil fractions as taught by FR '775 as evident by O'Connor or Daugherty, and select jojoba oil because it is suggested by FR '775 and because O'Connor and Daugherty teach that jojoba oil consisting of both saponifiable fatty acids and non-saponifiable fatty alcohol, and further one would use jojoba oil hydrolyzed by alkali metal hydroxide to provide salts of jojoba fatty acids as taught by US '746. One would have been motivated to do so because US '746 teaches that cosmetic composition comprising hydrolyzed jojoba oil when applied to the skin prevents and retains natural moisture level of the skin. One would have reasonably expected formulating gel cosmetic composition comprising hydrolyzed jojoba oil comprising saponifiable and unsaponifiable fractions wherein the composition prevents and retains natural moisture level on application to the skin.

Regarding the claimed amounts of saponifiable and non-saponifiable fractions, the prior art teaches 37.62-48.3% fatty alcohols (non-saponifiable) and 62-38-51.7% fatty acids (saponifiable). Therefore, the amounts and corresponding ratio overlaps with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges

disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05** [R-5].

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### Response to Arguments

11. Applicant's arguments filed 11/04/2010 have been fully considered but they are not persuasive.

Applicants argue that FR '775 does not teach the use of tandem reaction products from saponification of jojoba oil. FR 2471775 describes a cosmetic oil that contains a mixture of at least two vegetable oils and at least one previously extracted non-saponifiable fraction. Non-saponifiable fractions are limited to non-saponifiable fractions of soybean and avocado oils only. FR 2471775A does not describe the use of polar hydrophilic salts at all, let alone use of polar hydrophilic salts as a tandem reaction product of saponification of jojoba oil, as required by claims 35 and 38. What FR 2471775A teaches is the opposite -- separation (i.e., extraction) of the unsaponifiables from the salts and addition of the separated unsaponifiables to other organic material. At most, FR 2471775 teaches that the separated unsaponifiable portion may contain a fraction of saponifiable materials, but FR 2471775 does not teach that the separated unsaponifiable portion would contain any of the polar salts.

Art Unit: 1611

In response to this argument, it is argued that if FR '775 had disclosed hydrolyzed jojoba oil, it would have been an anticipatory reference. FR '775 however teaches composition comprising saponifiable and unsaponifiables fractions obtained from vegetable oils and suggested jojoba oil. Applicants themselves admit that "FR 2471775 teaches that the separated unsaponifiable portion may contain a fraction of saponifiable materials". The reference further teaches Carpopol 940 which is acidic gelling agent, and its mixture with jojoba oil will result into the same reaction as instantly claimed, including forming salts or neutralization. Applicants admit that FR '775 teaches the unsaponifiables from the salts and addition of the separated unsaponifiables to other organic material, and it is noted that the present claims recite "alkali salts of jojoba oil fatty acid and...non-saponifiable", as taught by the reference. The present claims directed to the whole jojoba oil encompassing saponifiable and unsaponifiable. Jojoba oil naturally contains both saponifiable and unsaponifiable fractions as evident by O'Connor and Daugherty. The reference teaches that unsaponifiables display interesting dermatological properties and used in cosmetics. Since FR '775 desired to have both fractions in a cosmetic composition, and the art recognized the presence of both fractions in jojoba oil and further recognized hydrolysis of jojoba oil is advantageous to the skin taught by US '746, then the present invention as a whole is taught by the combined teaching of the cited prior art.

Applicants argue that the present application is a continuation-in-part of U.S. Patent No. 7435424. The same art relied upon in the present application, FR 2471775A,

itself was also relied upon in originally rejecting Application Serial No. 09/478071, Patent No. 4324802 which claims priority to FR application no. 79 30956 (FR 2471775A), but that rejection was subsequently withdrawn.

In response to this argument, it is argued that the examiner cannot comment on the prosecution history of another patent application.

Applicants argue that FR 2471775A, either taken alone or in combination with Arquette as evident by O'Connor or Daugherty cannot render Applicants' amended claims obvious. Therefore, regardless of whether Arquette describes saponification, the combination of FR 2471775 and Arquette is inappropriate as neither of these references describe using the recombined fractions of saponified oil, jojoba oil or otherwise.

In response to this argument, it is argued that the present claims as a whole is taught by the combined teaching of the cited prior art. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide gel cosmetic composition comprising saponifiable and unsaponifiable oil fractions as taught by FR '775 as evident by O'Connor or Daugherty, and select jojoba oil because it is suggested by FR '775 and because O'Connor and Daugherty teach that jojoba oil consisting of both saponifiable fatty acids and non-saponifiable fatty alcohol, and further one would use jojoba oil hydrolyzed by alkali metal hydroxide to provide salts of jojoba fatty acids as taught by US '746. One would have been motivated to do so because US '746 teaches that cosmetic composition comprising hydrolyzed jojoba oil when applied to the skin prevents and retains natural moisture level of the skin. One would have reasonably

expected formulating gel cosmetic composition comprising hydrolyzed jojoba oil comprising saponifiable and unsaponifiable fractions wherein the composition prevents and retains natural moisture level on application to the skin. The contents of jojoba oil are constant and is considered intrinsic feature of jojoba oil. The saponification/hydrolysis of said oil necessarily leads to mixture of saponifiable and unsaponifiable. It is emphasized that according to the description of the present application, the starting material can undergo all type of processes before the hydrolysis, including reduction, double bond modified and hydrogenation.

Applicants argue that Arquette does not describe the products of saponified jojoba oil. Arquette instead describes alcoholysis. Applicants note that Floraesters 15, 20, 30, 60 and 70 refer to jojoba esters whereas the Floraesters K-20W Jojoba referred to in the examples in the present application refer to hydrolyzed jojoba esters and water.

In response to this argument, it is argued that the claimed percent of saponifiable to non-saponifiable fractions is the natural percentage of fatty acid to fatty alcohol as present in natural jojoba oil as evident by the article by O'Connor and the article by Daugherty, both are now of record. FR '775 teaches jojoba oil. It is further argued that US '746 teaches hydrolysis of jojoba oil using metal alkali in col.3, lines 58-60. US '746 teaches cosmetic composition comprising jojoba oil ester from the trade name Floraesters-15, 20, 30, 60 70, which applicant used in their examples instead of using the claimed composition. Trade name products should have the same fractions of saponified and unsaponified.

Art Unit: 1611

Applicants argue that, with respect to the claimed step of neutralizing the acidic gelling agent in said topical formulation with an effective amount of said composition, applicants argue that the emulsions described in FR 2471775A and the compositions described in Examples 1 and 2 of Arquette contain triethanolamine. In the present application, as claimed, the acidic gelling agent in the topical formulation prepared by Applicants' claimed method is neutralized with an effective amount of the composition itself and not an additional neutralizer such as triethanolamine.

In response to this argument, it is argued that all the elements of the present claims are taught by the combination of the prior art including jojoba oil fractions and acidic gel, and neutralization of acidic gel by the composition will be displayed by the composition taught by the combination of the prior art since materials and their properties are inseparable.

Applicants maintain that their amended independent claim 35 and previously presented claim 38 are patentably distinguishable from FR 2471775A "as evident by O'Connor" or "as evident by Daugherty" in view of Arquette.

The examiner believes that the combination of the references is proper and would have rendered the present invention prima facie obvious. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences

would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'I Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to

Art Unit: 1611

interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

Finally, it is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima* facie obvious within the meaning of 35 U.S.C. 103 (a).

#### Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1611

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

Art Unit: 1611

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG /Isis A Ghali/ Primary Examiner, Art Unit 1611